RESTRICTION/ELECTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-5 are drawn to a mucoadhesive composition comprising: either an anti-migraine drug or an anti-nausea drug; either a lipophilic carrier or a hydrophilic carrier; a mucoadhesive agent; and a sorption promoter, as classified in class 514, subclass 967.

II. Claims 6, 7, 9-11 and 21-30 are drawn to a method for treating either migraine and headache, or nausea and vomiting, without the aid of an intravaginal delivery device, wherein said method comprises intravaginally administering a formulation of said mucoadhesive composition, as classified in class 424, subclass 433.

III. Claims 8 and 12-16 are drawn to a method for treating either migraine and headache, or nausea and vomiting, with the aid of an intravaginal delivery device, wherein said method comprises intravaginally administering said intravaginal delivery device, which has a formulation of said mucoadhesive composition incorporated therein or coated thereon, as classified in class 424, subclass 431, and class 604, subclass 279.

IV. Claims 17-20 are drawn to an intravaginal device, as classified in class D03, subclass 203.5.

Inventions I and II are related as a product and a method of using said product without the aid of an intravaginal delivery device, respectively. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with

another materially different product; or (2) the product as claimed can be used by another method that is materially different from the instantly claimed method of using said product. In the instant case, a product as claimed in Invention I can be used by another method that is materially different from the method claimed in Invention II. For example, as opposed to administering said mucoadhesive composition intravaginally without the aid of an intravaginal delivery device as claimed in Invention II, a formulation of said mucoadhesive composition may alternatively be administered sublingually as opposed to intravaginally, wherein said mucoadhesive composition may further comprise a diuretic to offset water retention (i.e., "bloating"), which is often associated with menstruation.

Inventions I and III are related as a product and a method of using said product with the aid of an intravaginal delivery device, respectively. The inventions can be shown to be distinct if either or both of the following can be shown that: (1) the method of using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used by another method that is materially different from the instantly claimed method of using said product. In the instant case, a product as claimed in Invention I can be used by another method that is materially different from the method claimed in Invention III. For example, as opposed to intravaginally administering said mucoadhesive composition, which has been incorporated onto or within an intravaginal device as claimed in Invention III, a formulation of said mucoadhesive composition may alternatively be directly administered sublingually without the aid of a delivery device.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they have materially different designs, modes of operation, function, or effect. In the instant case, the composition claimed in Invention I has a function and effect of treating either migraine and headache, or nausea and vomiting, whereas the device claimed in Invention IV has a design, mode of operation, and function for being inserted directly into the vagina. As a result, the composition claimed in Invention I has a materially different function and effect from the device claimed in Invention IV, and are therefore unrelated.

Inventions II and II are unrelated. Inventions are unrelated if it can be shown that they have different modes of operation, different functions, or different effects. In the instant case, the method claimed in Invention II has a materially different mode of operation with respect to the method claimed in Invention III. More specifically, the method claimed in Invention II has a mode of operation of intravaginally administering a formulation of said mucoadhesive composition directly into the vagina without the aid of an intravaginal delivery device, whereas the method claimed in Invention III has a mode of operation that requires the aid of an intravaginal delivery device for intravaginally administering a formulation of said mucoadhesive composition into the vagina. As a result, the method claimed in Invention II has a materially different mode of operation from the method claimed in Invention III, and are therefore unrelated.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they have materially different designs, modes of operation, function, or effect. In the instant case, the method claimed in Invention II has a mode of operation

of intravaginally administering a formulation of said mucoadhesive composition directly into the vagina without the aid of an intravaginal delivery device, whereas the device claimed in Invention IV has a design, mode of operation, and function for being inserted directly into the vagina. As a result, the method claimed in Invention II has a materially different function and effect from the device claimed in Invention IV, and are therefore unrelated.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they have materially different designs, modes of operation, function, or effect. In the instant case, the method claimed in Invention III has a mode of operation of intravaginally administering a formulation of said mucoadhesive composition direction into the vagina with the aid of an intravaginal delivery device, whereas the device claimed in Invention IV has a design, mode of operation, and function for being inserted directly into the vagina. However, the device claimed in Invention IV need not necessarily comprise a mucoadhesive composition coated thereon or incorporated therein for the purpose of delivering a medicament, but may alternative be utilized solely for the function and effect of absorbing physiological fluids. As a result, the method claimed in Invention III has a materially different function and effect from the device claimed in Invention IV, and are therefore unrelated.

Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the art as shown by their difference classification, the prior art search required for each respective invention would be divergent, thereby causing an undue search burden. As a result, restriction for examination purposes is indicated as proper.

Applicants are therefore required under 35 USC § 121 to elect a single invention for prosecution on the merits.

Claims 1, 3-6, 9-12, 15-17, 22-25 and 30 are good generic to a plurality of disclosed patentably distinct species of drug, namely, anti-migraine drugs and anti-nausea drugs, and subspecies thereof, such as ergotamine and metoclopramide, respectively. In addition, claims 1-3, 6, 17, 21, 22, 29 and 30 are generic to a plurality of disclosed patentably distinct species of carrier, namely lipophilic carriers and hydrophilic carriers, and subspecies thereof, such as a monoglyceride fatty acid having a C_8 to C_{18} chain, or a polyehtylene glycol having a molecular weight between about 200 and 8000, respectively. In addition, claims 1-3, 6, 17, 21, 22, 27 and 30 are generic to a plurality of disclosed patentably distinct species of mucoadhesive agent (i.e., hydroxypropyl methylcellulose). In addition, claims 1-3, 6, 17, 21, 22, 28 and 30 are generic to a plurality of disclosed patentably distinct species of sorption promoter (i.e., ethoxydiglycol). In addition, claims 7, 8, 12, 17-20 and 26 are generic to a plurality of disclosed patentably distinct species of formulation (i.e., cream). Furthermore, claims 8 and 12-20 are generic to a plurality of disclosed patentably distinct species of intravaginal device (i.e., tampon).

Even though this requirement is traversed, Applicants are further required under 35 USC § 121 to elect, for search purposes only, a single disclosed patentably distinct species of: 1. drug (i.e., an anti-migraine drug) and a subspecies thereof (i.e., ergotamine); 2. carrier (i.e., a lipophilic carrier) and a subspecies thereof (i.e., a monoglyceride fatty acid having a C_8 to C_{18} chain); 3. mucoadhesive agent (i.e., hydroxypropyl methylcellulose); 4. sorption promoter (i.e., ethoxydiglycol); 5.

formulation (i.e., cream); and 6. intravaginal device (i.e., tampon); for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

The disclosed species are patentably distinct, each from the other, because they possess different molecular structures, as well as different physicochemical properties. Therefore, restriction for examination purposes as indicated is proper. In addition to including a listing of all claims, as well as any claims subsequently added thereto, which are readable upon the elected species, Applicants should also include a chemical structure or a molecular formula of the elected compounds, if a chemical structure or a molecular formula of said compound is not already contained within the instant specification. I f applicants are unable to provide the chemical structure or the molecular formula of said compound, the CAS (Chemical Abstract Service) number assigned to said compound will suffice.

In conclusion, The Examiner has required restriction between product and methods of use claims.

Applicants elect, with traverse, Group III, namely claims 8 and 12-16 to be examined in the current application. Applicants traverse Examiner requirement, at least for restriction of the Group I and II. Since the Examiner will be searching for device of Group II incorporated with or coated with the composition of claims 1-5, it is respectfully submitted that it would not add an additional burden on the Examiner to examine claims 1-5 as well as claims 6-7, 9-11 and 21-30, directed to a method using said composition for treatment of migraine and nausea without the device.

Concerning the species election, Applicants elect, for search purposes only, the following species:

a drug: an anti-migraine drug;

a drug subspecies: naratriptan;

a carrier: a hydrophilic carrier;

a carrier subspecies: PEG 6000/1500;

a mucoadhesive agent: hydroxypropyl methylcellulose;

a sorption promoter: ethoxydiglycol;

a formulation: a bioadhesive system; and

an intravaginal device: a foam.

It is understood that the species election is made for search purposes only and that if no generic claim is finally held allowable during case prosecution on the merits, the claims shall be restricted to these species.

However, it is further to be understood that when Applicants elected claims directed to a method, and the method claims are subsequently found allowable, the other withdrawn methods of use that include all the limitations of the allowable claims will be rejoined.

SUMMARY

In summary, prior claims 1-30 are canceled and the new claims 31-45 are added. These claims are drawn to the claims of the elected group III. Examination of the new claims is respectfully requested.

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Respectfully Submitted,

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